EFFECTIVENESS OF MUSIC THERAPY ON PAIN AND PHYSIOLOGICAL PARAMETERS AMONG PATIENTS ON MECHANICAL VENTILATION AT KMCH, COIMBATORE

Reg. No. 301610453

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A DISSERTATION SUBMITTED TO THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

OCTOBER 2018

CERTIFICATE

This is to certify that the dissertation entitled **"A STUDY TO ASSESS THE EFFECTIVENESS OF MUSIC THERAPY ON PAIN AND PHYSIOLOGICAL PARAMETERS AMONG PATIENTS ON MECHANICAL VENTILATION AT KMCH, COIMBATORE"** is submitted to the faculty of nursing, **THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI,** by **Register No. 301610453** in partial fulfilment of requirement for the degree of Master of Science in Nursing. It is the bonafide work done by him and the conclusions are his own. It is further certified that this dissertation or any part thereof has not formed the basis for award of any degree, diploma or similar titles.

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SL NO	ACRONYMS	ABBREVATIONS
1	CPOT	Critical Care Pain Observation Tool
2	PCV	PRESSURE CONTROL VENTILATION
3	CPAP	Continues Positive Airway Pressure

CHAPTER I
INTRODUCTION

“PAIN CAN BE ENDURED AND DEFEATED ONLY IF IT IS EMBRACED. DENIED OR FEARED, IT GROWS.”

DEAN KOONTZ.

INTRODUCTION

Mechanical ventilation is a lifesaving and frequently used treatment modality for a variety of medical diagnoses in the Intensive Care Unit (ICU). Despite this fact, mechanical ventilation may be a distressing experience for the patient and may result in a decrease in comfort. ((Wong, 2001)

Pain is a commonly reported experience among mechanically ventilated patients that influences their health status. Patients in critical care units are subject to intensive nursing care interventions such as repositioning, breathing and coughing exercises, tracheal suctioning, and line removals that add to their painful experiences. The increased pain level among patients will, consequently, result in deteriorating the respiratory and cardiac functions, increase morbidity and mortality, prolong the recovery period, and increase health care costs. Despite advancements in pain management, pain remains a significant problem for mechanically ventilated patients in critical care units. (Chen ,2011)

Pain is an unpleasant feeling often caused by intense or damaging stimuli, such as stubbing a toe, burning a finger, putting alcohol on a cut. The International association for the study of pain widely used definition states: "Pain is an unpleasant

sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". The body naturally responds to pain with symptoms of high pain; increased heart rate and blood pressure, shallow breathing, sweaty palms and knotted muscles. The sympathetic nervous system is aroused and stress hormones are released resulting in feelings of anxiety. These physiological responses can result in an increased perception of pain. (Young,2006)

Non-pharmacologic approaches can often help divert attention from pain to alternate sensory experiences, which can further change the affective component of the pain experience. Non-pharmacological pain management can be an effective pain management tool. Cognitive and behavioral non-pharmacological approaches have been associated with postoperative pain recovery and can be important approaches, particularly in short hospital stays. Pharmacological agents were reported to delay mechanical ventilation weaning process. Therefore, non-pharmacological strategies to manage mechanically ventilated patients' stress are recommended. (Tracy, 2013).

Research shows that music therapy helps individuals of all ages with 78 health concerns ranging from aggressive behavior in children to urinary concerns of the elderly. It Improves blood flow: Studies showed Separate studies show that music therapy decreases the pain and, stress. Music therapy aids recovery after surgery as shown by several studies, reducing pain and lessening the use of postoperative analgesics and has its impact on physiological measures (e. g. blood pressure and cholesterol; measurements by ECG, EEG). Music therapy helps reduce pain for many sufferers with, neuropathy patients, and hemodialysis patients. (Choi, 2010**)**

Music therapy is a cost-effective, non-invasive method, which can be simply applied by nurses, alongside other nursing strategies. The ideal music for therapeutic purposes and stress relief is characterized by a steady rhythm, a low frequency, a relaxing melody and a beat pattern of 60-80 beats per minute. Application of music therapy, as a branch of alternative medicine, has been proposed for the promotion of health indicators and music therapy as a nursing intervention can lead to a decline in treatment side-effects and medical costs. (Akombo, 2006)

Need for the Study

"PAIN AND DEATH ARE A PART OF LIFE. TO REJECT THEM IS TO REJECT LIFE ITSELF."

- ELLIS, HAVELOCK

Pain is the fifth vital sign. Its management is central to the care of critically ill patients but is sometimes misunderstood and poorly executed by nurses. Pain is frequently a barrier to caring, hemodynamic stability and healing. (Taylor C,2005).

Mechanical ventilation is a lifesaving and frequently used treatment modality for a variety of medical diagnoses in the Intensive Care Unit (ICU). Despite this fact, mechanical ventilation may be a distressing experience for the patient, and may result in pain, decrease in comfort. Ventilated patients are susceptible to numerous stressors such as pain, fear, agitation, anxiety, communication problems, and loss of control. (Dijkstra bm,2010)

In ICU patients, both inadequate and excessive sedation are potentially harmful. Inadequate sedation may increase the risks of adverse events, such as accidental self-extubation, with subsequent acute respiratory insufficiency due to upper airway collapse, loss of venous catheters, and injury to self or others. However, excessive sedation can lead to respiratory depression, hypotension and bradycardia or prolonged duration of mechanical ventilation. (Davis, 2013).

Pharmacological pain management confers both benefits and harms. Although sedation and analgesia have improved significantly in recent years, nurses are often concerned that adverse drug reactions may compromise the patient. Analgesics are not free of adverse effects, such as sedation, emesis, anxiety, agitation or delirium, prolongation of mechanical ventilation or hospital stay and increased healthcare costs. (Tobias,2011).

Nurses rely heavily on these types of medical interventions to treat pain and anxiety, but they do not incorporate enough nursing interventions to increase and promote comfort. We frequently administer intravenous sedative medications to ventilated patients to counteract the negative effects of treatment. The interventions to promote comfort of mechanically ventilated patients may be beneficial and may decrease the need for these medications. Music therapy is one of the interventions that have been investigated within the context of comfort for mechanically ventilated patients. (Khorshid, 2011)

Music therapy is defined as “a major branch which we make use of music and musical activities to meet people’s physical, psychological, social and mental needs” and accepted as a scientific treatment method compatible with traditional medicine Now-a-days, music therapy as a treatment intervention that supports traditional Medicine is used as a non-invasive treatment method for patients in the ICU. However, use of music in nursing or as a nursing intervention is quite rare in our country. (McCaffrey & Locsin, 2012)

Listening to relaxing music reduces biochemical markers of stress, depression, and disability; promotes sleep and relaxation; improves quality of life, comfort, and analgesia; reduces heart rate, blood pressure, body temperature, respiration rate, and pain; and stimulates electroencephalographic waves, which are related to endorphin release, relaxation, pain relief, and lowered blood pressure and heart rate. (Demir, 2012)

Statement of the Problem

A Study to Assess the Effectiveness of Music Therapy on Pain and Physiological Parameters among Patients on Mechanical Ventilation at KMCH, Coimbatore.

Objectives

Objectives of the study were to,

- Assess the level of pain and physiological parameters among patients on mechanical ventilation.

- Evaluate the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation.
- Associate the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic variables.

Hypotheses

On the basis of objectives of study, the following hypotheses have been formulated.

H_1: There is a significant difference between the mean pre-test and post-test level of pain and physiological parameters among participants in the music therapy group

H_2: There is a significant difference between post-test level of pain and physiological parameters of participants in the music therapy and conventional care group

H_3: There is a significant association between the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic variables.

Operational Definition

Music therapy

In this study it refers to the pre-recorded validated music (violin) played by Dr.Bharathi which is administered to experimental group using head phone, for about 20 minutes.

Pain

Pain is the distressing experience reflected through the observable changes in facial expression, body movements, muscle tension and compliance with ventilator as measured by Critical Care Pain Observation Tool (CPOT).

Physiological parameters

In this study, it refers to the physiological changes that occur due to pain includes heart rate, blood pressure and respiratory rate.

Assumption

Music therapy helps promote health and wellbeing of mechanical ventilated patients.

Conceptual Framework

The conceptual framework refers to interrelated concepts or abstract those are assembled together in same rational scheme by virtue of their relevance to a common theme (Polit and Hungler (2017)

It is developed with the aid of reviewing research findings, investigators experience and comprehension. The illustrative representation of ideas and concepts help the investigator to transfer the ideas to others easily. It gives a 'concrete' basis for 'abstract' ideas.

The research study is based on the conceptual framework developed by Ernestine Weidenbach known as Helping Art of Clinical Nursing Theory which is otherwise known as The Prescription theory. Ernestine Weidenbach's theory

defines nursing as a practice of identifying a patient's need for help through the observation of presenting behaviour and symptoms, exploration of the meaning of those symptoms, determination of the cause of discomfort, the determination of the patient's ability to resolve the discomfort, or determining if the patient has a need of help from the nurse or another health care professional. Model has prescriptive theory within and is based on three factors such as central purpose, prescription and realities.

Central purpose

According to Ernestine Weidenbach central purpose refers to what the nurse wants to accomplish, which the nurse recognizes as essential to the particular discipline. It is the overall goal towards which the nurse strives. It consists of activities directed towards the patients good.

In this study the central purpose is music therapy administered among mechanically ventilated patients. The central purpose of this conceptual framework is achieved through three stages, which includes Identification of need for help, ministering the needed help and validation of provided help.

Identification of Need for help

According to Weidenbach, nursing practice consists of identifying a patient's need for help. Identification involves the patient as an individual with unique experiences and understanding the perception of the condition. It determines the patient's need for help based on the existence of a need. A need for help is defined as any measure desired by the patient that has the potential to restore or extend the ability to cope with various life situations that affect health and wellness.

In the current study the mechanically ventilated patients require music therapy to reduce pain and physiological parameters in order to improve their health status. Patients' base line status was assessed through demographic data. Pain was measured by CPOT scale, and physiological parameters such as heart rate, blood pressure and respiratory rate were also assessed.

Ministering the Needed Help

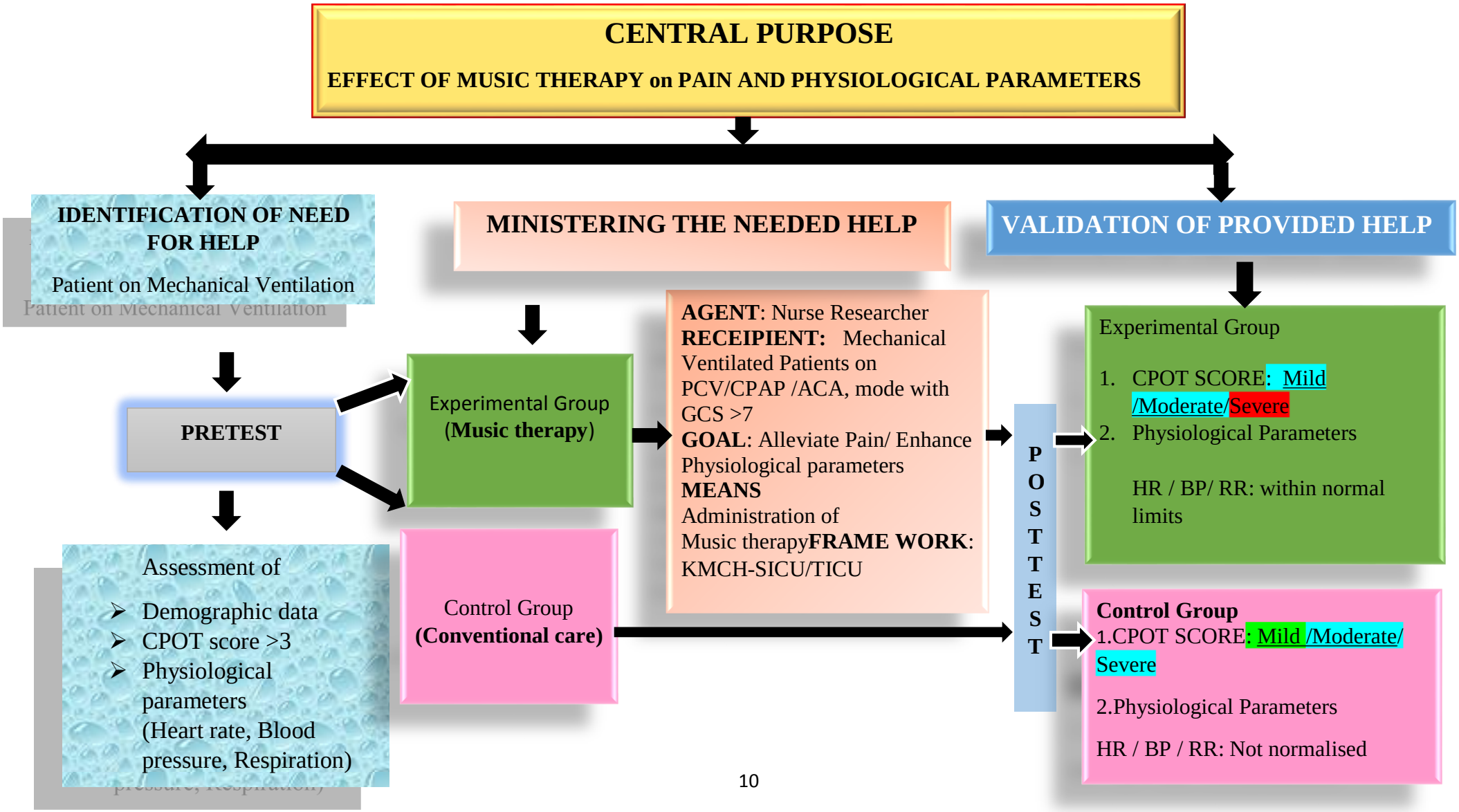
It is referred as provision of needed help. In this study the need was met by means of administering music therapy.

Validating the Needed Help

According to Weidenbach Validation refers to a collection of evidence that shows whether the patient's needs have been met and whether his functional ability has been restored as a direct result of the nurses' action. It is based on the outcome which indicates goal attainment. If the outcome is negative then the feedback will be done by re-evaluation. In this study validation was done by outcome measurement. Investigator validated whether the need for quit smoking has been met or not. This was measured by means of post-test knowledge score.

Post test was conducted after 20 minutes of music therapy administration. The outcome pain relief as measured through CPOT was categorized as mild moderate and severe. The physiological parameters such as heart rate, blood pressure and respiratory rates should range within normal limits. The outcome of the study indicated patients' pain relief and enhanced physiological parameters. Feedback process and revaluation of needs were not planned in this study.

Figure 1 : Conceptual framework: Modified weiden bach (1958) helping art of clinical nursing theory



CHAPTER II
REVIEW OF LITERATURE

Review of literature is systematic identification, selection, critical analysis, and reporting of existing information on the topic of material for the study. Review of literature is important for having a broad understanding of the problem. "The material gathered in the literature review should be treated as an integral part of research data. Since what is found in the literature can not only have an influence which is important on the formalities of the problem and the design of research but also provides useful comparative material when the data collected in the research is analysed".

A literature review uses as its database report of primary or original scholarship and dose not report new primary scholarship itself. In this study the review of literature was done from text book, published journals, articles and electronic sources. The useful and relevant literature for the present study have been organized and presented under the following sub headings.

Review of literature is presented under following headings:

Selection 1: Literature related to Pain and physiological parameters among patients on mechanical ventilation.

Selection 2: Literature related to Effect of music therapy on pain and physiological parameters.

2.1 Literature related to Pain and physiological parameters among patients on mechanical ventilation.

Pain is developed, when there is certain illness or injury. Patients under mechanical ventilator commonly experience pain, which is often overlooked. Factors such as stage of illness, invasive-procedures, and surgical interventions often aggravate pain in critical patients. Non-experimental study was done to assess pain levels among mechanically ventilated patients during routine nursing procedures by using the behavioral pain scale among 30 mechanically ventilated patients admitted in Intensive Care Unit, in Down Town hospital Guwahati, Assam. Fifteen patients were assessed during turning and fifteen patients were assessed during endotracheal tube suctioning. Purposive sampling technique was used to obtain the sample. It was concluded that patients under mechanical ventilation experienced pain during routine nursing procedures. (Betbhalin ,2017)

Mechanical ventilation leads to decreased comfort, Pain and anxiety may increase during this treatment modality, and the literature suggests this may directly affect patient comfort levels. Music therapy as a nursing intervention within the context of comfort, pain, and anxiety of mechanically ventilated patients was investigated. A convenience, purposive sampling was used. The sample consisted of 2 men and 3 women. Dependent variables measured included comfort, pain, and anxiety. Physiologic dependent measures included heart rate, respiratory rate, and systolic and diastolic blood pressure collected at timed intervals. Pain was measured using the Numerical Graphic Rating Pain Scale. Comfort, anxiety, and pain scores before and after the intervention and control also did not demonstrate significance. (Jamie Marie Besel, 2006)

Mechanical ventilation is a part of the most frequently used technological treatments in Intensive Care Units (ICU). The purposive sample of 15 mechanically ventilated patients was recruited for this phenomenological study to collect the data during one month by using semi structured interviews. Data was analyzed by thematic analysis method. A total of 11 sub themes and three main themes were identified. All these themes were reflections of intra personal, extra personal and interpersonal experiences of the patients. The feeling of inner suffering such as pain, dependency, fear and anxiety, thirst, noise level, cold environment and nightmares were identified while on mechanical ventilation. Mechanically ventilated patients tolerate many stressors during mechanical ventilation at moderate to high levels of distress. (Marasinghe, 2015)

The pain in patients with low consciousness is a major challenge in the intensive care unit. Therefore, the use of behavioral tools for pain assessment could be an effective tool to manage pain in this group of patients. This study was to determine the effects on pain management by nurses using a critical care pain observational tool in patients with a decreased level of consciousness. The research used a before and after design to evaluate the ability of nurses to manage pain in patients with low consciousness. A total of 106 ICU nurses were included in the study. The study was divided into three phases: pre-implementation, implementation, and postimplementation. The researchers first observed the nurse's management of pain in their patients; this was done three times using a checklist following tracheal suctioning and position change procedures. The nurses were then taught how to apply the critical-care pain observational tool (CPOT). The performance scores after training improved with relation to the nurse's diagnosis of pain, reassessment was done, and re-relieving of any pain. (Ahmad ,2015)

2.2. Literature related to effect of music therapy on pain and physiological parameters.

To evaluate the perception of oncology patients with chronic pain as to the effects of music in alleviating pain, to identify if there were changes in the vital signs of these patients before and after the musicotherapy session, and to identify whether the intensity of pain is diminished after the music session as per an analogic scale of pain. This level II, descriptive-exploratory and cross-sectional study used a quantitative and qualitative approach. The sample consisted of ten oncology patients with chronic pain. There was a reduction in vital signs and in intensity of pain in ten patients of the sample; after the music sessions, the patients reported a sensation of relief of pain, relaxation, and a belief in the power of music as a supplementary therapy. Music showed an influence in reducing vital signs and pain intensity, and the patients perceived a reduction of pain and anxiety and began to believe in music as a form of therapy. **(**Mariana,2009**)**

S.e. Hosseini, 2013, investigated the effects of music-therapy on labor pain and progress in parturient primipara. The subjects of this research were 30 women, got selected voluntarily and were put in either experimental or control group. The experimental group listened to a relaxing music for 30 minutes in each hour for a two-hour period and the control group was not exposed to music. For the purpose of gathering data in both groups, the pain score was measured through visual analogue painscale. The results showed the effect of music on the decrease of sensation of pain in the experimental group as compared to control group.

A clinical trial study was conducted on 86 patients who underwent open heart surgery to assess the impact of preferred music on the pain intensity and physiological parameters of patients. The pain intensity and physiologic parameters were measured in both groups after surgery when the patient enteredin the ward, at first. Then, in experimental group, in addition to the usual nursing care, the music preferred by the patient was played for 20 min using headphones and Mp3 player. In control group, pain intensity and physiologic parameters were recorded within 20 min after using the headphones without playing the music. After the end of intervention, pain intensity and physiologic parameters of the both groups were measured again. The study concluded that using the preferred music in patients after coronary artery bypass surgery significantly reduced the pain and diastolic blood pressure and increased the blood oxygen saturation level in the experimental group and no difference was observed in other physiologic parameters after intervention. (Seyedoshohadaee, 2017)

The effect of music therapy on pain, and patient satisfaction was assessed who were present to the emergency department in Turkey. This controlled and experimental study was conducted in the emergency department of a hospital in Turkey between July and October 2012. The study sample consisted of 200 patients in total, 100 forming the intervention group and 100 being the control group, the Visual Analog Scale was used to measure the patients' level of painin the study. The questionnaires of the intervention group were administered after playing the music. When the intervention and control groups were compared, it was observed that there was a significant decrease in the VASP and STAI-S scores in favour of

the intervention group. The results showed that music therapy had a positive effect in terms of reducing the severity of pain in patients and noted only a very small portion of the patients were not pleased to listen to music in the emergency department. (Parlar Kilic,Karadag, 2015)

A controlled, single-blind, randomized trial study assessed the usefulness of music intervention on management of patients with chronic pain. Eighty-seven patients presenting with lumbar pain, fibromyalgia, inflammatory disease, or neurological disease were included in the study. During their hospitalization, the intervention arm (n=44) received at least 2 daily sessions of music listening between D0 and D10, associated with their standard treatment, and then pursued the music intervention at home until D60 using a multimedia player in which the music listening software program had been installed. The control arm received standard treatment only (n=43). The end points measured at D0, D10, D60, and D90 were: pain (VAS), anxiety-depression (HAD) and the consumption of medication. The study concluded that the music intervention method utilized appeared to be useful in managing chronic pain as it enabled a significant reduction in the consumption of medication. (Marie-Christine Picot,2011)

A randomized controlled trial was conducted on music therapy in order to reduce pain among patients on mechanical ventilation. In 10 months period they admitted 60 patients receiving mechanical ventilation support to intervention (n=30), and control arms (n=30) of a pragmatic parallel group randomized controlled trial. Participants in both arms wore head phones for 90 minutes. Those in the intervention arm heard pleasant natural sound, while those in the control arm

heard nothing. Outcome measures reported the self-reported Visual Analog Scale for pain at baseline and 30, 60, 90 minutes into the intervention. The trial arms were similar at baseline. In the intervention arm, pain scores fell and were significantly lower than in the control arm at each time point($P<0.05$). the study concluded that the administration of pleasant natural sounds via headphones as a simple, safe, non-pharmacologic nursing intervention that may be used to allay pain for up to 120 minutes in patients receiving mechanical ventilation support**.** (v saadatmand,2015)

A prospective, randomized, double-blind study was conducted in the intensive care unit among patients on mechanical ventilation at Sahloul Teaching Hospital over a period of 4 months. Patients who were on mechanical ventilator and GCS more than 7 were included. Patients who had previous history of mechanical ventilation were excluded. Before induction, patients wore headphones linked to an MP3 player. They were randomly allocated into 2 groups: Group M (with music) and group C (without music). Physiological parameters and pain experienced were recorded. One hundred and forty patients were included and allocated into 2 groups that were comparable in demographic characteristics and physiological parameters. Comparison of these two groups regarding the physiological parameters found were more stabile in group M (with music) for systolic arterial blood pressure. **(**Mohamed Kahloula, 2017)

Pain is the common phenomenon among the patients in Intensive Care Unit and can be due to invasive procedures, mechanical ventilation and physical situation of ICU. The clinical trial study was conducted among 90 eligible patients who were selected conveniently and then were randomly allocated into three music therapy,

reflexology and control groups of 30 persons in intensive care unit in one educational hospital in 2015. Intervention was carried out through playing instrumental music of Arnd Stein in 3 sessions of 30 minutes via headphone. In reflexology group, intervention was done for 30 minutes once a day for three consecutive days. Control group only received the routine care about pain relief. The pain was measured Behavioural behavioral Pain Scale, 5 minutes before and immediately after the interventions. In control group, measurement was done with the same interval and frequency. The study conclude that the application of complementary methods such as music and reflexology could reduce the intensity of pain in patients with loss of consciousness. (Fariba Yaghoubinia, Ali Navidian,2016)

The purpose of study was to determine whether therapeutic music affects the patient's perception of pain, postoperative day 1 after knee replacement surgery in an inpatient hospital. The study was an analysis of the quantity of opioids the patient had requested, the length of stay, and the physiological parameters, which included blood pressure, heart rate, respiratory rate, and oxygen saturation. Sixty knee replacement patients were randomly placed in the music group or the quiet group. The Faces Pain Scale Revised with Numeric Rating Scale was used to measure pain levels. Statistical analysis between the music group and the quiet group indicated a significant difference in patient's pain levels ($F = .298$; $p = .037$). Study results supported music therapy in decreasing patient's perception of pain and recommended nurses to suggest music intervention to decrease pain as an evidence-based practice. (Heather E. Hooks,2014)

Seunghee Margevicius, 2012, conducted a study to deal with efficacy of a single music therapy session to reduce pain in palliative care patients. Two hundred inpatients at University Hospitals Case Medical Center were enrolled in the study from 2009 to 2011. Patients were randomly assigned to one of two groups: standard care alone (medical and nursing care that included scheduled analgesics) or standard care with music therapy. A clinical nurse specialist administered pre- and post-tests to assess the level of pain using a numeric rating scale as the primary outcome, and the Face, Legs, Activity, Cry, Consolability Scale and the Functional Pain Scale as secondary outcomes. The intervention incorporated music therapist-guided autogenic relaxation and live music. A significantly greater decrease in numeric rating scale pain scores was seen in the music therapy group ($P<0.0001$). Mean changes in Face, Legs, Activity, Cry, Consolability scores did not differ between study groups. Mean change in Functional Pain Scale scores was significantly greater in the music therapy group. The study concluded that a single music therapy intervention incorporating therapist-guided autogenic relaxation and live music was found to be effective in lowering pain in palliative care patients.

Hatice Ciftci, 2015 investigated the effect of music on pain, anxiety and comfort in patients who were in the intensive care unit (ICU) with the diagnosis of Cerebrovascular Accident (CVA). Target population of this experimental study was all CVA patients who were hospitalized in the ICU of a state hospital located in Adana, Turkey. The participants were 72 patients and data were collected through Patient Identification and Vital Signs Form, Visual Analogue Scale (VAS) for identifying the level of pain, Faces Anxiety Scale and State Trait Anxiety Inventory

for identifying the level of anxiety, and General Comfort Questionnaire for identifying the level of comfort. The VAS score, State Anxiety Level, and Faces Anxiety Scale score decreased considerably with music therapy. The study concluded that the music therapy was effective in contributing the comfort of ICU patients by decreasing the pain and anxiety.

A prospective randomized clinical trial was conducted in a tertiary hospital, with a before and after intervention measurement. The study determined the effect of music therapy in postoperative pain among obese patients who underwent a major abdomen surgery. Data were collected from overweight or obese postoperative patients (n=87), who were randomly separated in two groups, the "music therapy" group (n1=45) and the "non - music therapy" group (n2=42 subjects). Visual Analogue Scale (VAS) was used for pain perception. The period of the study was 3 months. The patients in two groups had normal mean values in heart rate, respiration rate and SpO2, before and after the intervention, without any special abnormalities. Those patients who received music therapy, twice postoperatively, referred more decreased, and the compare to the non-music patients group, which their Δ-VAS score was less decreased. Thus music therapy in the acute postoperative period was found to be useful intervention tool, in order to promote patients' comfort and more tolerable perception against pain.(Michail Zografakis Sfakianakis,2017)

Sook Kwon,2006, conducted a study to determine the effects of music therapy on pain, discomfort, and depression for patients with leg fractures. Data was collected from 40 patients admitted in an orthopaedic surgery care unit. The subjects

included 20 intervention group members and 20 control group members. Music therapy was offered to intervention group members once a day for 3 days for 30 and 60 minutes per day. Pain was measured with a numeric rating scale and by measuring vital signs. The result demonstrated that the music therapy was an effective method for decreasing pain and discomfort for patients with leg fractures.

Priyadharshini Krishnaswamy, Shoba Nair, 2016 analysed the effect of music therapy on pain scores and anxiety levels of cancer patients with pain. In this quantitative study, a comparative study was done on fourteen cancer patients admitted for pain relief under the Department of Pain and Palliative Medicine, of a tertiary care hospital, having moderate to severe pain (numerical pain rating scale [NRS]. Convenience sampling was used. Patients were allocated to test group or control group nonrandomly. The test group patients were subjected to music therapy for 20 min while the control group patients were kept occupied by talking to them for 20 min. The NRS scale was used to assess the pre- and post-interventional pain scores and the Hamilton anxiety rating scale was used to assess the pre- and post-interventional anxiety scores in the two groups. Music therapy was found to lower the pain score of a patient who had received standard palliative care for pain reduction.

CHAPTER -III
RESEARCH METHODOLOGY

Research methodology is the systematic, theoretical analysis of the methods applied to a field of study. It comprises the theoretical analysis of the body of methods and principles associated with a branch of knowledge. **(Vishnu S Warrier, 2017)**

Research Design

The research design used for this study was true experimental Pretest and posttest control group design.

Experimental group: O_1 **X** O_2

Control group: O_1 O_2

O_1 Pretest assessment of experimental group and control group

X Music therapy

O_2 Posttest assessment of experimental group and control group

Research Variables

Independent variable - Music therapy

Dependent variables - Pain and Physiological parameters

Demographic variables - Age, sex, educational status, occupation and monthly income, habits, other co-morbidity.

Setting of the Study

The study was conducted at KMCH hospital Coimbatore. It is an NABH accredited multi-specialty hospital catering to a population of 850 bed capacity with all modern technology. Patients who were admitted in TICU (12 beds) and SICU-I (14 beds) were included in the study.

Population

All patients on mechanical ventilation.

Sampling Technique

Samples were selected by non-probability purposive sampling technique.

Sample Size

Totally 60 samples were recruited and among 60 samples, 30 were allocated as experimental group and 30 samples as control group for the study.

Criteria for Sample Selection

Inclusion Criteria

- The patients on mechanical ventilation.
- The patients with PCV and CPAP ventilatory modes,
- Patients who had GCS more than 7
- Patients who received Injection Fentanyl (low sedation)

Exclusion Criteria

- Patients who had previous history of mechanical ventilation
- Patients who were fully paralyzed with medication
- Patients with pulmonary disorders

Description of the Tool

Section I : Demographic variables patients on mechanical ventilation

Section II : CPOT scale to assess the pain of the individual.

Section III : Performance of music therapy for pain and physiological parameters

Section A: Demographic Variables

It is a self-administered questionnaire with the demographic variables such as age, sex, educational status, occupation and monthly income, habits, other co-morbidity.

Section B: Critical Care Pain Observation Tool (Cpot)

CPOT scale is a standardized tool, which is been used extensively in all routine practices at KMCH ICU set up. The scale has four components viz, facial expressions, body movements, muscle tension, ventilation compliance and measures pain with movements each have the score of 0, 1 and 2.

Section C: Performance Of Music Therapy For Pain And Physiological Parameters

Performance of music therapy is to evaluate the pain and physiological parameters. The music are pre recordable voilin music to play with mp3 player using with headphone to playing 20 minutes

Testing of the tool

Content Validity

Content validity refers to the degree to which an instrument measures what it is supposed to measure. The content validity of the present tool along with the evaluation criteria checklist was submitted to 4 experts in the field of medicine, medical surgical nursing, for their opinion on the items in the tool. As per expert opinion minimal modifications were made in clinical and demographic variables.

Reliability of the tool

The reliability of the tool was tested using Crohnbach's Alpha method for Critical Care Pain Observation Tool (CPOT) r -0.85. Hence the tool was considered highly reliable for proceeding with the main study.

Pilot Study

The pilot study was conducted for a period of one week. The investigator obtained formal permission from the respective authorities to conduct the pilot study. The patients are selected based on the inclusion and exclusion criteria, after assessing pretest and the samples were using music (violin) for about 20 minutes. After Post-test were assessed the pain and physiological parameters. The result of pilot study revealed that the study was feasible.

Data Collection Procedure

Ethical committee clearance was obtained from the Chairman, Principal and Head of the Department (Intensive Care Unit) to conduct the study in TICU and

SICU. The study was approved by the ethical committee of KMCH. The demographic and clinical characteristics of the patient were collected at the time of data collection.

Data was collected for totally 60 samples from TICU and SICU. The patients for the study were selected based on inclusion criteria each day subjects were selected by means of systematic sampling method and were assigned in two groups namely experimental and control groups. Pre-test was conducted for both the groups, and then intervention (music therapy) was administered for the experimental group. The experimental group received music therapy for 20 minutes which was played using and after which the post-test was conducted. Similarly, for the control group, the subjects were assessed for pre-test pain level without administration of music therapy followed by post-test done after routine care along with the experimental group.

Plans for data analysis

The data collected was analysed by means of descriptive statistics, and inferential statistics.

Descriptive Statistics

1. Analysis of the baseline data was done by using frequency and percentage.
2. Level of pain among patients with mechanical ventilator was analysed by computing frequency, percentage, mean, standard deviation.

Inferential Statistics:

1. Paired “t” test, unpaired “t” test was used to find out the effectiveness of music therapy on the level of pain.
2. Chi-square analysis was used to determine the association between the level of pain and selected demographic variables among patients on mechanical ventilation.

CHAPTER - IV
DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of data collected to evaluate the effectiveness of music therapy on level of pain and physiological parameters among patients on mechanical ventilation.

The analysis of data involves the translation of the information collected during the course of the research project into interpretable, convenient and descriptive terms and to draw inferences from them using statistical methods. The purpose of analysis is to summarize, compare and test the proposed relationships and infer findings. The collected data was tabulated and analyzed using descriptive and inferential statistical in order to meet the objectives of the study, and to test the hypotheses.

The data collected were interpreted under the following sections.

Section: I

Description of demographic variables and clinical variables of patients on mechanical ventilation.

Section: II

Description of level of pain assessed through CPOT among patients on mechanical ventilation.

Section: III

Effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation in experimental and control group.

Section: IV

Association of level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic and clinical variables.

SECTION - I

Table 1: Distribution of study participants according to demographic variables

Demographic variables		Group			
		Experiment(n=30)		Control(n=30)	
		N	%	N	%
Age	20 -30 years	3	10	7	23
	30 -40 years	7	23	9	30
	40 -50 years	5	17	6	20
	>50 years	15	50	8	27
Sex	Male	24	80	24	80
	Female	6	20	6	20
Education status	Primary education	10	33	4	13
	Secondary education	4	13	7	24
	Graduate	11	37	15	50
	Illiterate	5	17	4	13
Occupation status	Private	12	40	17	57
	Government	1	3	1	3
	Self employed	8	27	5	17
	Unemployed	9	30	7	23
Monthly income	< Rs.10,000	4	13	6	20
	Rs.11,000 to 20,000	16	53	14	47
	Rs.21,000 to 30,000	5	17	4	13
	> Rs.31,000	5	17	6	20

Demographic variables		Group			
		Experiment(n=30)		Control(n=30)	
		N	%	N	%
Marital status	Married	28	93	27	90
	Unmarried	2	7	3	10
	Separated	0	0	0	0
	Living alone	0	0	0	0
Co-Morbidity	Diabetic mellitus	4	13	4	13
	Hypertension	3	10	3	10
	CAD	0	0	0	0
	DM +HT	6	20	2	7
	Nil	17	57	21	70

From the above table, with regard to age 50% (15) of them belongs to 50 years and above and 30% (9) of them were used between 30 – 40 years, in experimental and control group respectively Majority 80% (24) of them were males in both. With regard to education, 36.67% (11) of them were graduates in experimental and 50% (15) in control group. About 40% (12) were private employed in experimental group, whereas in control group this figured more than 57% (17). More than half of them in experimental group were drawing a monthly income of Rs 11,000-20,000, in were as control group this scored about 47% (14). Majority were married in both groups. There was no associated co-morbidity found in experimental group 57% (17) and control group70% (21).

The above demographic variables were also depicted in figures as follows

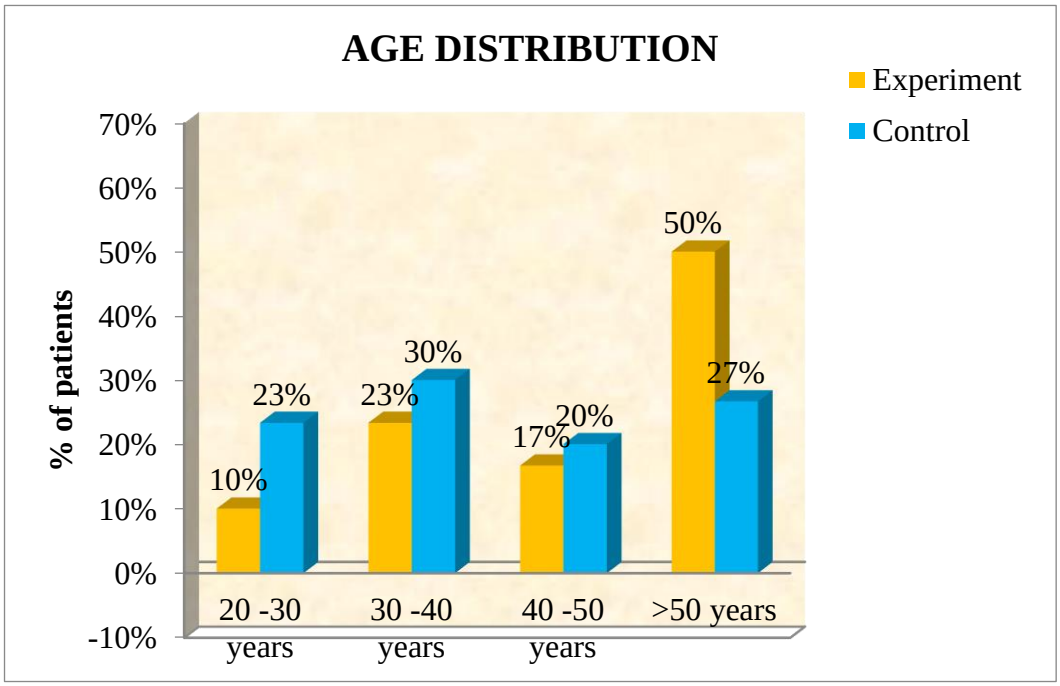


Figure: 2 Distribution of study participants based on age

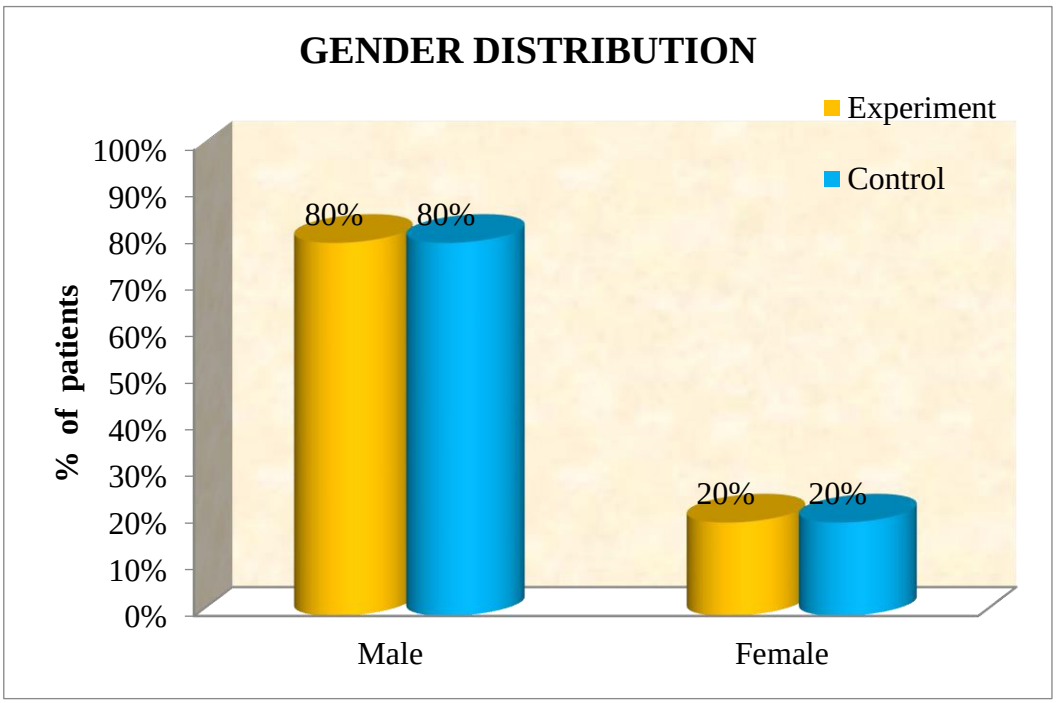


Figure: 3 Distribution of study participants based on sex

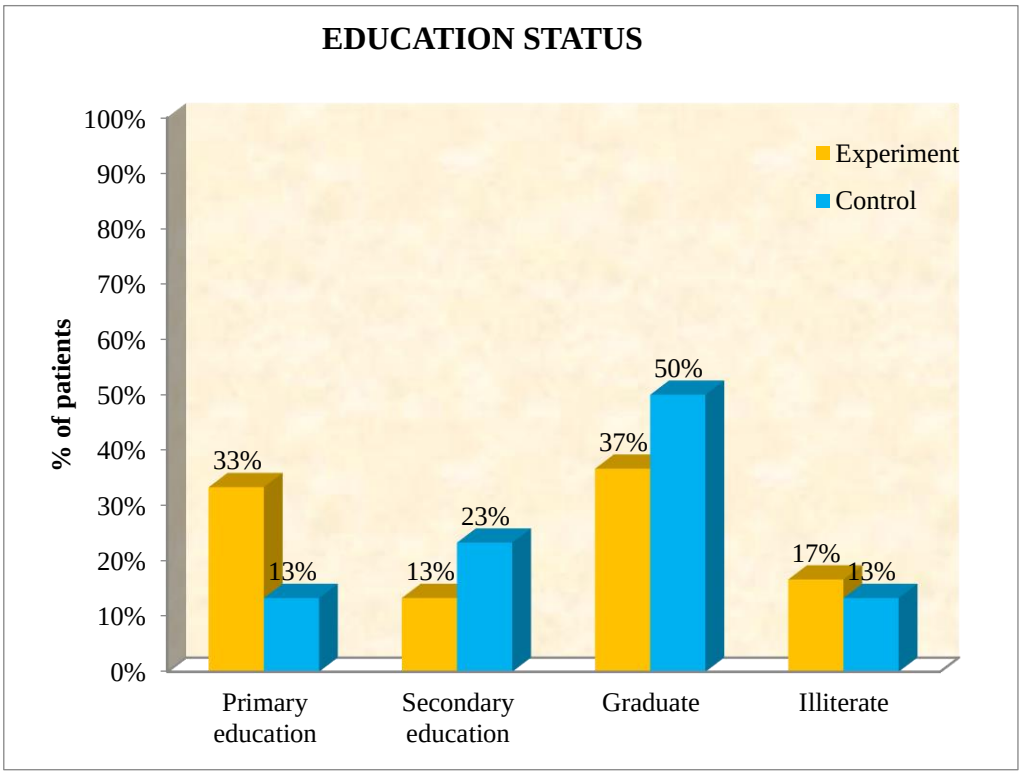


Figure :4 Distribution of study participants based on education

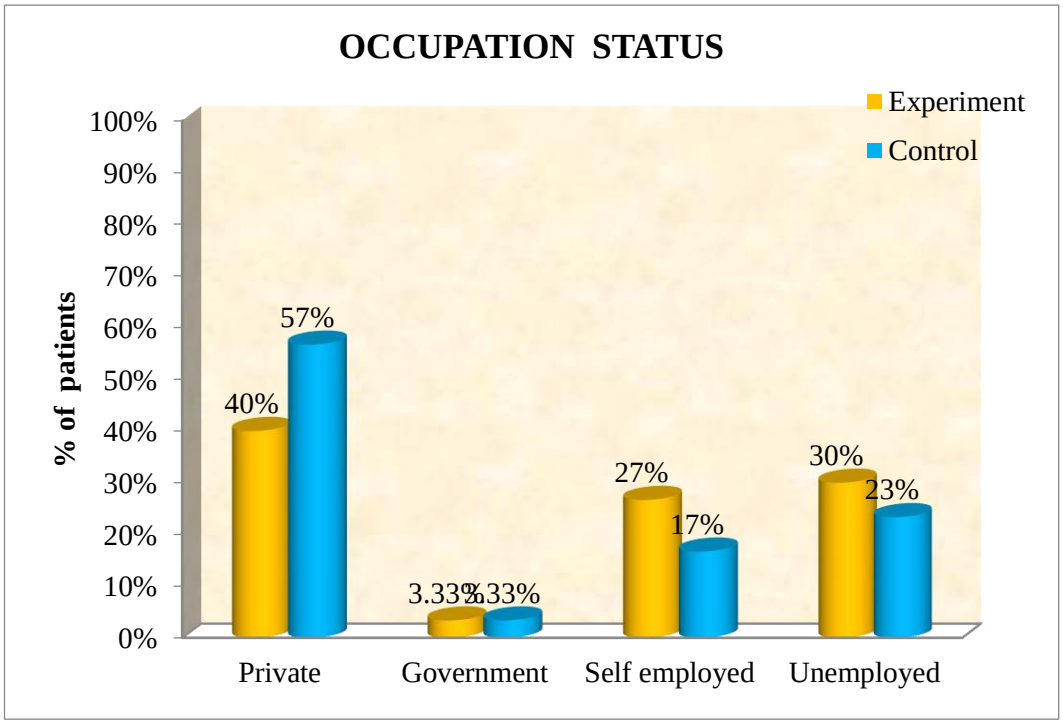


Figure : 5 Distribution of study participants based on occupation status

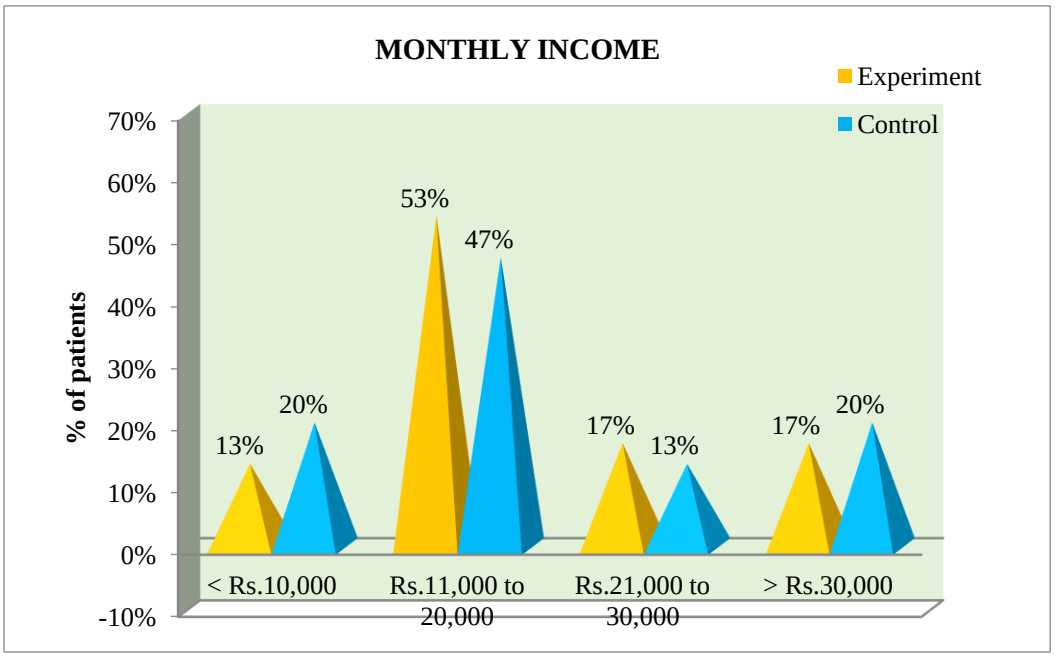


Figure : 6 Distribution of study participants based on monthly income

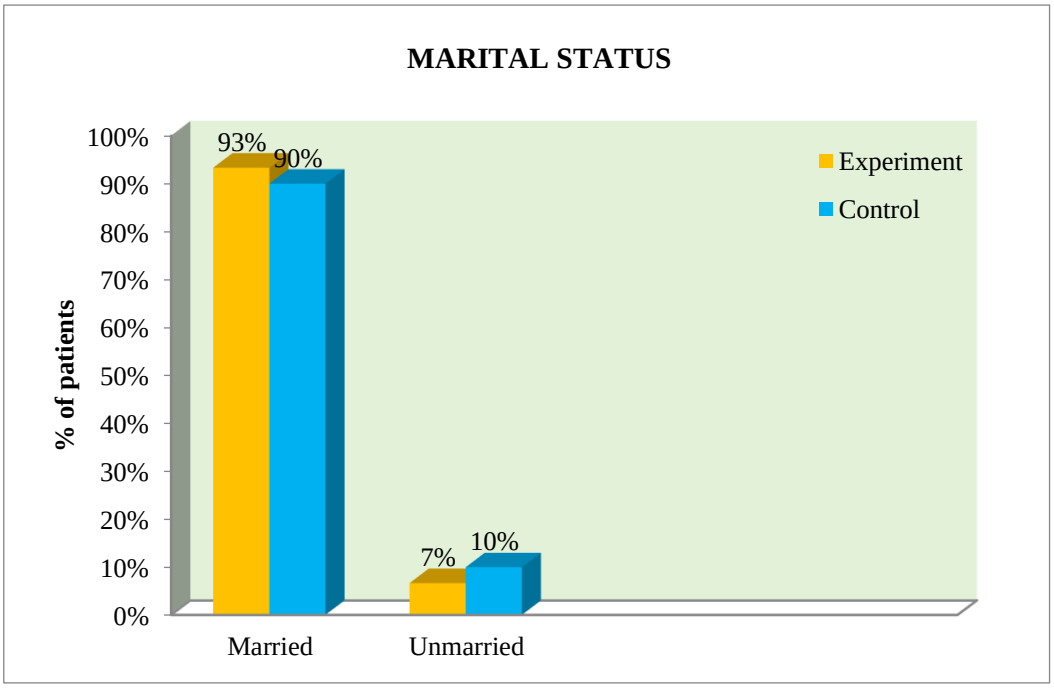


Figure : 7 Distribution of study participants based on marital status

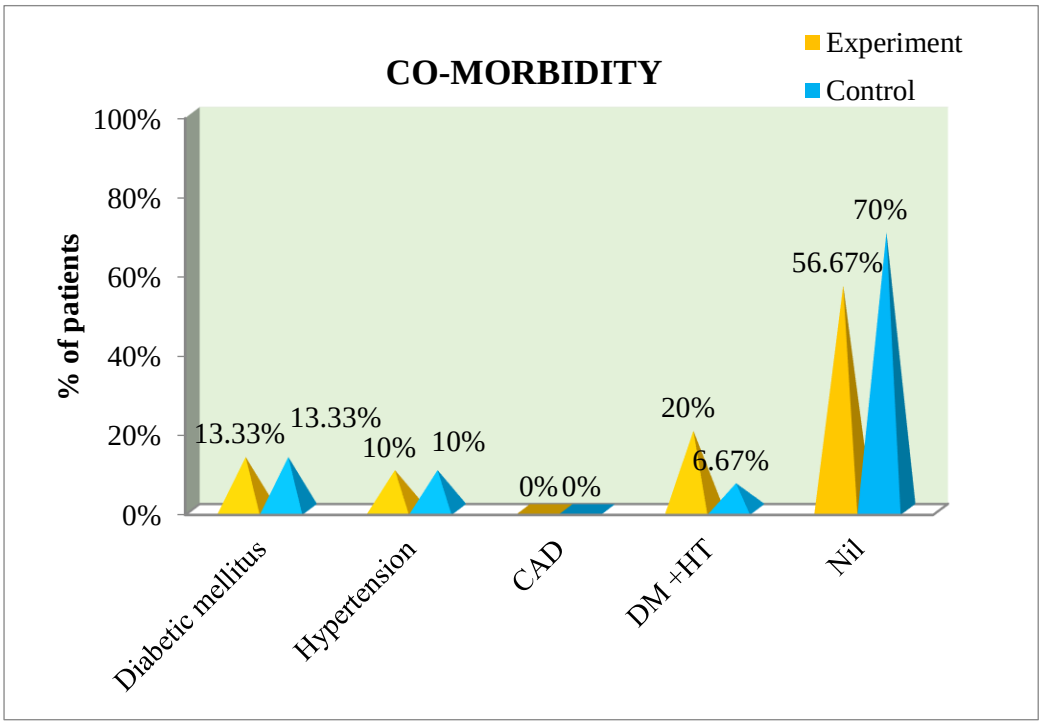


Figure: 8 Distribution of study participants based on co morbidity

Table – 2: Distribution of study participants according to Baseline physiological parameters

Physiological parameters		Group			
		Experiment(n=30)		Control(n=30)	
		n	%	n	%
	41 -60 beats	4	13	5	17
	61 -80 beats	19	63	15	50
	81 -100 beats	7	23	8	27
	>100 beats	0	0	2	6
Systolic pressure	81 -100 mm\hg	0	0	0	0
	101 -120 mm\hg	7	23	7	23
	121 -140 mm\hg	16	53	14	47
	>140 mm\hg	7	23	9	30
Diastolic pressure	41 -60 mm\hg	2	7	6	20
	61 -80 mm\hg	21	70	19	63
	81 -100 mm\hg	7	23	5	17
	101 -120 mm\hg	0	0	0	0
Respiration	11-20 breaths	14	47	10	33
	21-30 breaths	14	47	17	57
	>30breaths	2	6	3	10
Mode of Ventilation	CPAP	13	43	17	57
	PCV	17	57	13	43

The above table shows that the physiological parameters of the study subjects. The heart rate, in experimental group 63% (19) and in control group 50% (15) ranged between 61 - 80 beats. The systolic pressure in experimental 53% (16) and control group 46 % (14) were between 121 - 140 mm/Hg. The diastolic pressure in experimental group 70% (21) and control group 63% (19) were between 61-80 mm/Hg. In experimental group about 47 % (14) of them had 11 - 20 breaths. But in control group similar percentage had 21 - 30 breaths. There were 43% (13) subjects in experimental and 57 % (17) in control group were on CPAP, this was reverse in PCV mode.

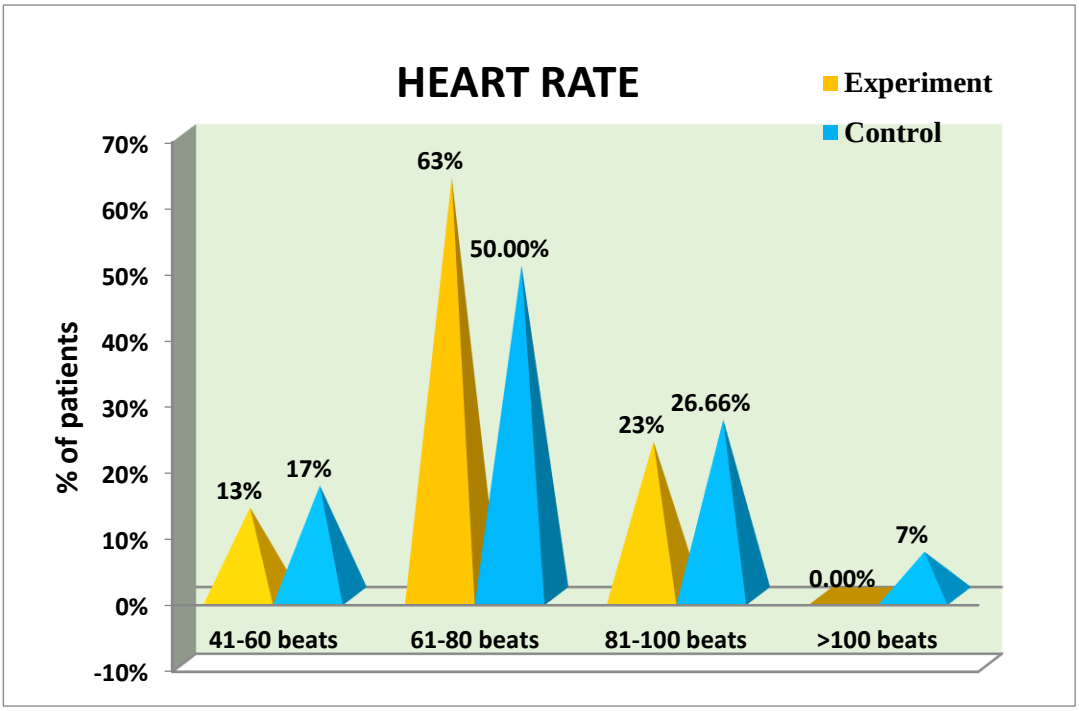


Figure : 9 Distribution of study participants based on Heart rate

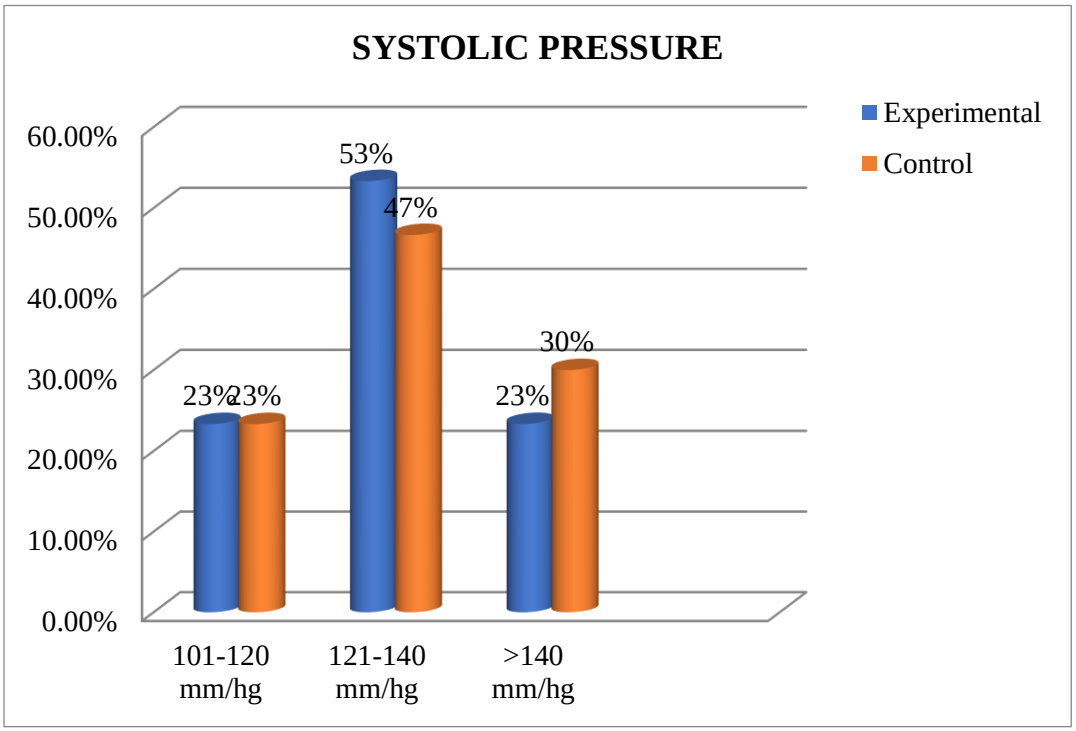


Figure : 10 Distribution of study participants based on systolic pressure

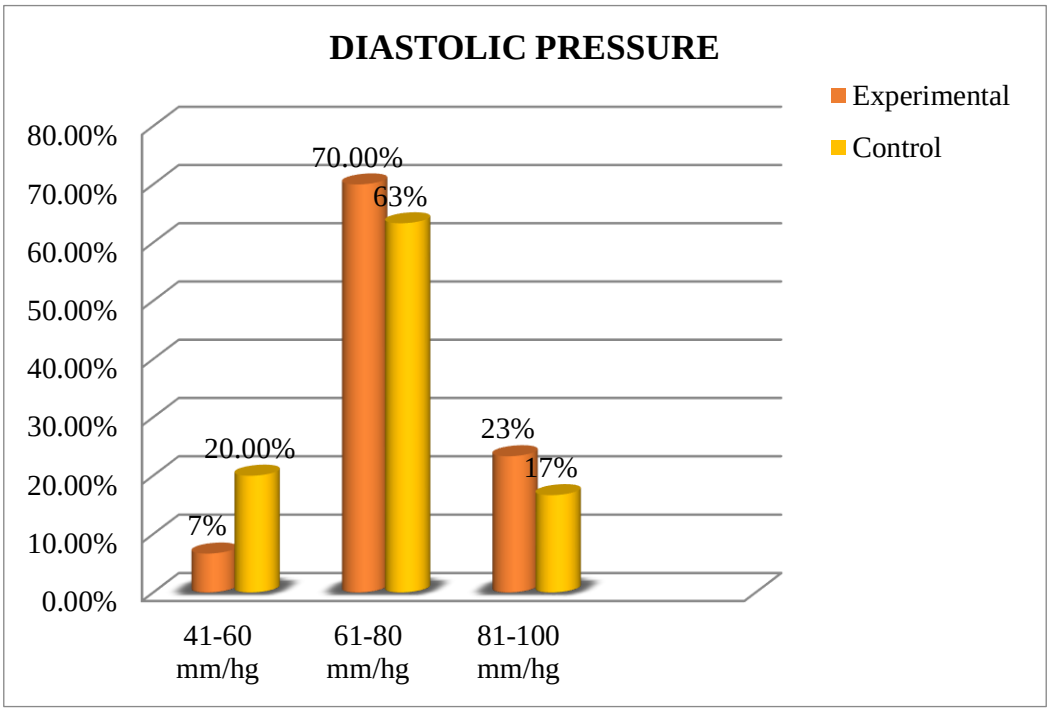


Figure : 11 Distribution of study participants based on diastolic pressure

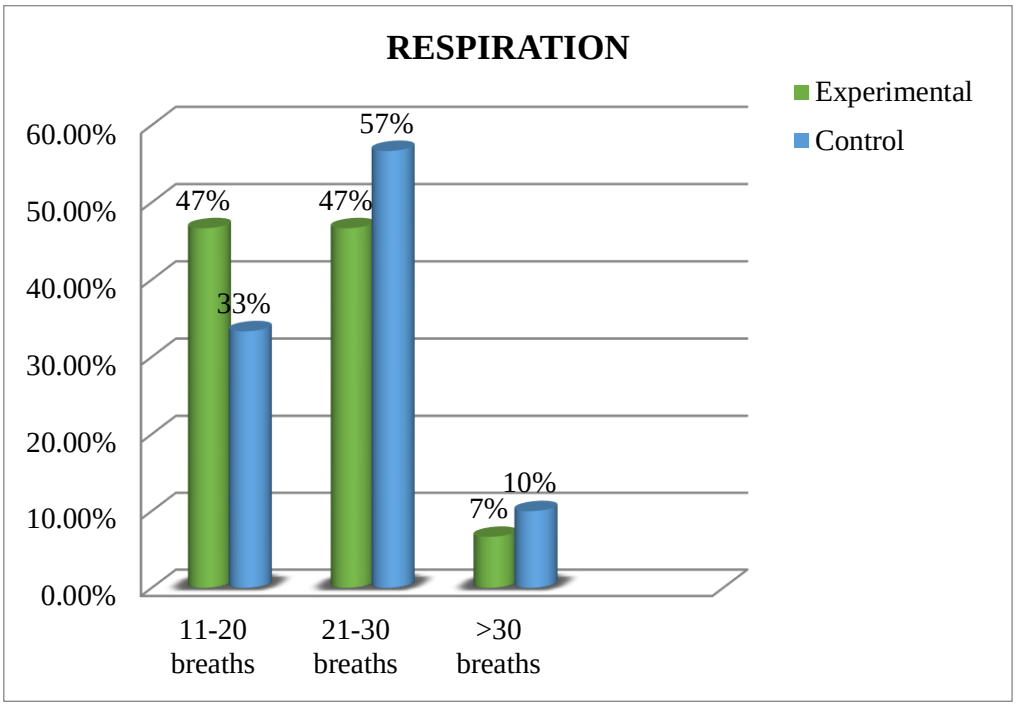


Figure : 12 Distribution of study participants based on respiration

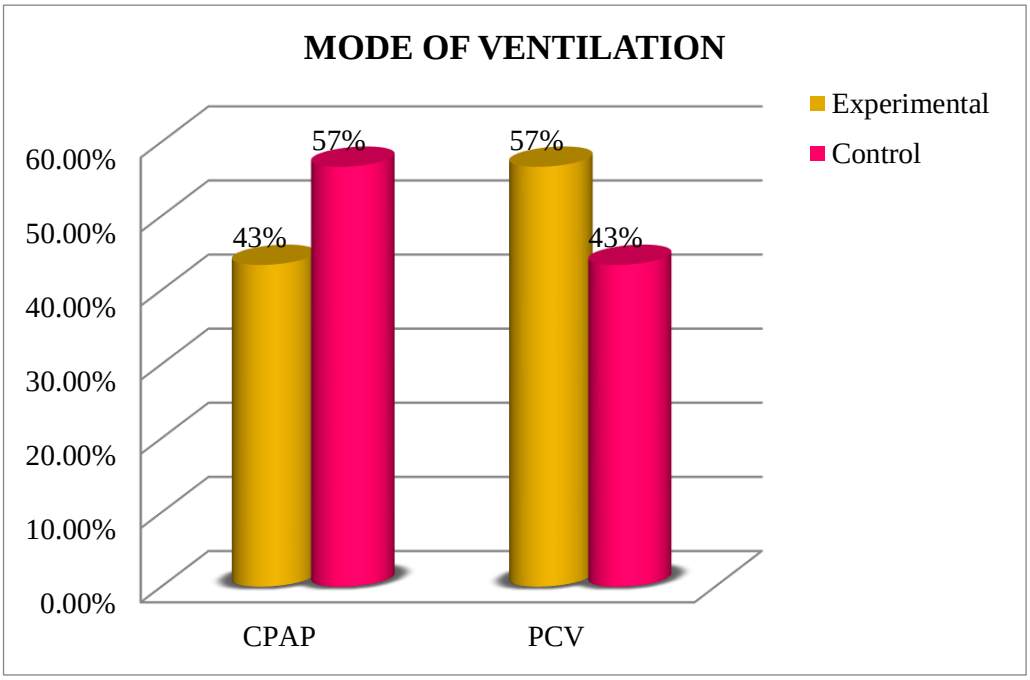


Figure : 13 Distribution of study participants based on mode of ventilation

SECTION - II

Table-3: distribution of study participants pretest level of pain among patients on mechanical ventilation in experimental and control group.

CPOT	Group			
	Experiment		Control	
	N	%	n	%
Mild	0	0	0	0
Moderate	22	83	26	87
Severe	5	17	4	13
Total	**30**	**100**	**30**	**100**

The above table shows the pre-test levels of pain. In experimental group83%(22) of them had moderate pain and 17% (5) of them had severe pain. In control 87%(26) of them had moderate pain and 13%(4) of them had severe pain.

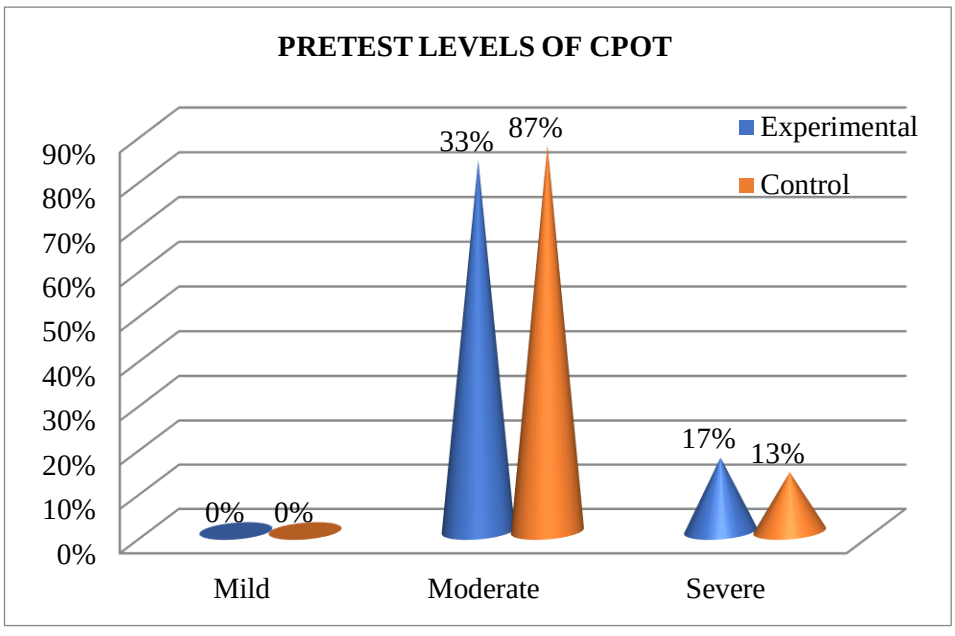


Figure : 14 Distribution of study participants based on pretest level of pain among patients on mechanical ventilation in experimental and control group

Table-4: distribution of study participants post-test according to level of pain among patients on mechanical ventilation in experimental and control group.

CPOT	Group			
	Experiment		Control	
	N	%	N	%
Mild	21	70	0	0
Moderate	9	30	26	87
Severe	0	0	4	13
Total	**30**	**100.00%**	**30**	**100.00%**

The above table shows the post-test level of pain. In experimental group 70% (21) had mild pain and 30%(9) of them had moderate pain where as in control group 87%(26) of them had moderate pain and 13% (4) of them had severe pain.

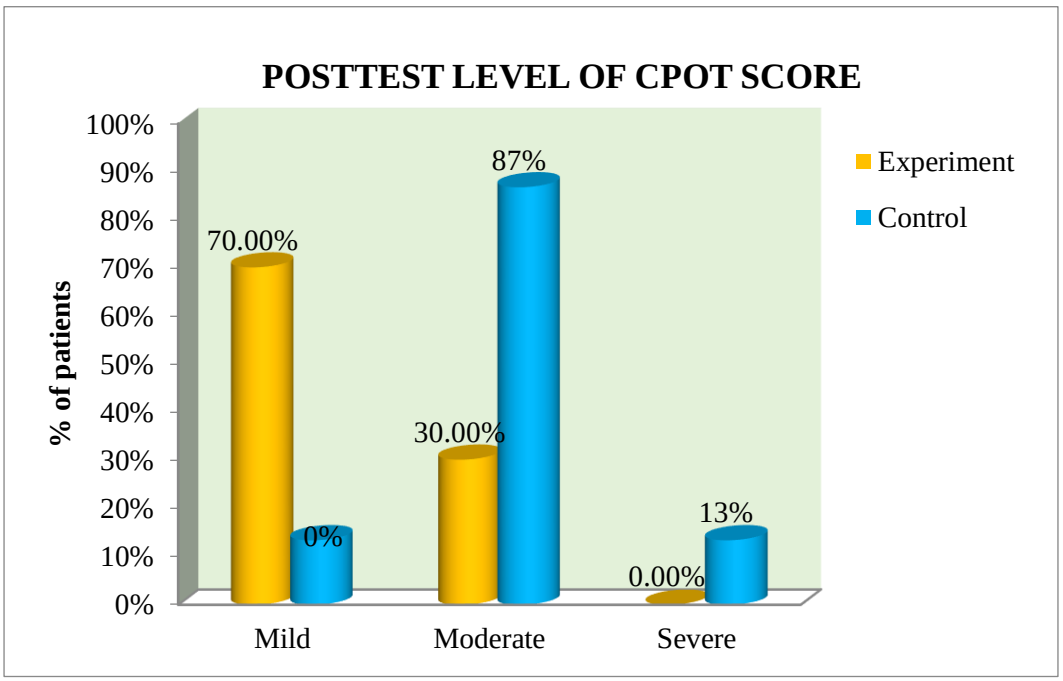


Figure 15 Distribution of study participants based on post-test level pain among patients on mechanical ventilation in experimental and control group

SECTION - III

Table: 5 Effectiveness of music therapy on pain among patients on mechanical ventilation in experimental group.

	Pretest		Post-test		Mean Difference	Paired t-test
	Mean	**SD**	**Mean**	**SD**		
CPOT	**6.13**	**.93**	**3.00**	**1.20**	3.13	t=12.63 P=0.001*** (S)

*** P<0.001 very highly significant S=significant

In experimental group, the paired t-test shows significant difference between pretest CPOT mean score 6.13 with the SD of 0.93 and post-test 3.00 with the SD of 1.20. The mean CPOT scores 3.13 also shows significance at p< 0.001 level which proves the effectiveness of music therapy.

Table: 6 Effectiveness of music therapy on physiological parameters among patients on mechanical ventilation in experimental group.

	Pretest		Posttest		Mean Difference	Paired t-test
	Mean	SD	Mean	SD		
Heart rate	2.17	0.64	2.19	0.71	0.02	t=1.12 P=0.05(S)
Systolic Blood Pressure	3.00	0.69	2.60	0.72	0.72	t=0.48 P=0.02* (S)
Diastolic Blood pressure	2.17	0.53	2.00	0.45	0.08	t = 1.11 P=0.048*(S)
Respiration	1.67	0.71	1.53	0.14	0.14	t = 0.95 P=0.049*(S)

P>0.05 not significant NS= not significant

The above table reveals that in pretest the experimental group had their mean (SD) heart rate score as 2.17 (0.64) and systolic blood pressure as 3.00 (0.69) and diastolic blood pressure score was 2.17 (0.53) and respiratory rate score was 1.67 (0.71). In experimental group post-test were heart rate score was 2.19 (0.71) and systolic blood pressure score was 2.60 (0.72), and diastolic blood pressure score was 2.00(0.45) and respiratory score was 1.53 (0.14). Significant difference was found between pretest and posttest systolic blood pressure, diastolic blood pressure and respiratory scores except heart rate .

Table: 7 Comparison of pretest and posttest pain level among patients on mechanical ventilation in control group.

	Pretest		Posttest		Mean Difference	Paired t-test
	Mean	SD	Mean	SD		
CPOT	6.00	1.14	5.58	.63	0.02	t=2.48 P=0.05* (S)

* P<0.05 significant S=significant

In control group, the paired t-test shows significant difference between pretest CPOT mean score 6.00 with the SD of 1.14 and posttest 5.58 with the SD of 0.63. The mean CPOT scores 0.02 also shows significance at p< 0.05 level which proves control group it is not on par with the effect of music therapy in experimental group.

Table: 8 Comparison of pretest and posttest physiological parameters among patients on mechanical ventilation in control group

	Pretest		Posttest		Mean Difference	Paired t-test
	Mean	SD	Mean	SD		
Heart rate	2.23	0.14	2.13	0.12	0.10	t = 1.79p= 0.083(NS)
Systolic Blood Pressure	3.07	0.13	3.03	0.12	0.04	t = 0.57 p = 0.057(NS)
Diastolic Blood pressure	2.00	0.10	1.97	0.10	0.03	t= 1.00 p= 0.32(NS)
Respiration	1.77	0.11	1.63	0.47	0.14	t = 1.43 p= 0.16(NS)

P >0.05 not significant NS= not significant

The above table reveals that in pretest the control group had their mean (SD) heart rate score as 2.23 (0.14) and systolic blood pressure as 3.07 (0.13) and diastolic blood pressure score was 2.00 (0.10) and respiratory rate score was 1.77 (0.11). In post-test are heart rate score was 2.13 (0.12) and systolic blood pressure score was 3.03 (0.12), and diastolic blood pressure score was 1.97(0.10) and respiratory score was 1.63 (0.14). No Significant difference was found between pretest and posttest systolic blood pressure, diastolic blood pressure and respiratory scores

Table: 9 Comparison of pretest and posttest pain and physiological parameters level among patients on mechanical ventilation in experimental and control group

	Experiment		**Control**		**Mean Difference**	**Independent t test**
	Mean	**SD**	**Mean**	**SD**		
CPOT (posttest)	3.00	1.20	5.43	0.63	2.43	t = 9.82 P=0.001*** (S)

P>0.05 not significant NS= not significant, *** P<0.01 very highly significant S=significant

The above table reveals that in posttest, the experimental CPOT score as 3(1.20). In control group score was 5.43 (.63). The significant difference between experiment and control group of CPOT scores proves music therapy effectiveness.

	Experimental group		Control group			
	Post test		Posttest		Mean Difference	Independent t-test
	Mean	SD	Mean	SD		
Heart rate	2.19	0.71	2.13	0.12	0.16	t=6.22 p= 0.001***(S)
Systolic Blood Pressure	2.60	0.72	3.03	0.12	0.53	t= 5.67 p= 0.02*(S)
Diastolic Blood pressure	2.00	0.45	1.97	0.10	0.03	t= 7.42 p=0.02*(S)
Respiration	1.53	0.14	1.63	0.47	0.10	t= 7.16 p=0.001**(S)

***P <0.01 very highly significant, S= significant, *p<0.05 significant

The above table reveals that in post-test the experimental group had their mean (SD) heart rate score as 2.19 (0.71) and systolic blood pressure as 2.60 (0.72) and diastolic blood pressure score was 2.00 (0.45) and respiratory rate score was 1.53 (0.14). In control group post-test are heart rate score was 2.13 (0.12) and systolic blood pressure score was 3.03 (0.12), and diastolic blood pressure score was 1.97(0.10) and respiratory score was 1.63 (0.14). experimental group was Significant difference found in experimental post-test and control group post-test s was no significant in physiological parameters.

SECTION -IV

Table: 10 ASSOCIATION BETWEEN POSTTEST CPOT SCORE AND DEMOGRAPHIC VARIABLES (Experiment)

Demographic variables		Post-test CPOT						n	Chi square test
		Mild		Moderate		Severe			
		n	%	n	%	n	%		
Age	20 -30 years	3	100.0%	0	0.0%	0	0.0%	3	$\chi 2=2.24$ P=0.52 (NS)
	30 -40 years	5	71.4%	2	28.6%	0	0.0%	7	
	41 -50 years	4	80.0%	1	20.0%	0	0.0%	5	
	>50 years	9	60.0%	6	40.0%	0	0.0%	15	
Sex	Male	19	79.2%	5	20.8%	0	0.0%	24	**$\chi 2=4.80$P=0.02*(S)**
	Female	2	33.3%	4	66.7%	0	0.0%	6	
Education status	Primary education	6	60.0%	4	40.0%	0	0.0%	10	$\chi 2=1.49$ P=0.68 (NS)
	Secondary education	3	75.0%	1	25.0%	0	0.0%	4	
	Graduate	9	81.8%	2	18.2%	0	0.0%	11	
	Illiterate	3	60.0%	2	40.0%	0	0.0%	5	
Occupation status	Private	10	83.3%	2	16.7%	0	0.0%	12	$\chi 2=4.33$P=0.22(NS)
	Government	1	100.0%	0	0.0%	0	0.0%	1	
	Self employed	6	75.0%	2	25.0%	0	0.0%	8	
	Unemployed	5	55.5%	4	44.5%	0	0.0%	9	

Demographic variables		Post-test CPOT						n	Chi square test
		Mild		Moderate		Severe			
		n	%	n	%	n	%		
Monthly income	< Rs.10,000	1	25.0%	3	75.0%	0	0.0%	4	**χ2=8.57 P=0.03* (S)**
	Rs.11,000 to 20,000	10	62.5%	6	37.5%	0	0.0%	16	
	Rs.21,000 to 30,000	5	100.0%	0	0.0%	0	0.0%	5	
	> Rs.30,000	5	100.0%	0	0.0%	0	0.0%	5	
Marital status	Married	19	67.9%	9	32.1%	0	0.0%	28	χ2=0.91 P=0.33 (NS)
	Unmarried	2	100.0%	0	0.0%	0	0.0%	2	
	Seperated	0	0.0%	0	0.0%	0	0.0%	0	
	Living alone	0	0.0%	0	0.0%	0	0.0%	0	
Co-Morbidity	Diabetic mellitus	2	50.0%	2	50.0%	0	0.0%	4	χ2=3.82 P=0.28 (NS)
	Hypertension	1	33.3%	2	66.7%	0	0.0%	3	
	CAD	0	0.0%	0	0.0%	0	0.0%	0	
	DM +HT	3	50.0%	3	50.0%	0	0.0%	6	
	Nil	15	88.2%	2	11.8%	0	0.0%	17	

The above table shows the association between posttest level of CPOT score and demographic variables among experiment group. There was strong association between CPOT scores with demographic variable male patient and an income ranged 10, 000-20,000.

Table11: ASSOCIATION BETWEEN POSTTEST CPOT SCORE AND DEMOGRAPHIC VARIABLES (Control)

Demographic variables		Post-test CPOT						N	Chi square test
		Mild		Moderate		Severe			
		n	%	n	%	n	%		
Age	20 -30 years	2	28.6%	5	71.4%	0	0.0%	7	$\chi 2=2.85$ P=0.41 (NS)
	30 -40 years	0	0.0%	9	100.0%	0	0.0%	9	
	41 -50 years	1	16.7%	5	83.3%	0	0.0%	6	
	>50 years	1	12.5%	7	87.5%	0	0.0%	8	
Sex	Male	2	8.3%	22	91.7%	0	0.0%	24	$\chi 2=5.60$ P=0.11(NS)
	Female	2	33.3%	4	66.7%	0	0.0%	6	
Education status	Primary education	1	25.0%	3	75.0%	0	0.0%	4	$\chi 2=1.09$ P=0.79 (NS)
	Secondary education	1	14.3%	6	85.7%	0	0.0%	7	
	Graduate	2	13.3%	13	86.7%	0	0.0%	15	
	Illiterate	0	0.0%	4	100.0%	0	0.0%	4	
Occupation status	Private	2	11.8%	15	88.2%	0	0.0%	17	$\chi 2=7.31$ P=0.06(NS)
	Government	1	100.0%	0	0.0%	0	0.0%	1	
	Self employed	0	0.0%	5	100.0%	0	0.0%	5	
	Unemployed	1	14.3%	6	85.7%	0	0.0%	7	
Monthly income	< Rs.10,000	1	16.7%	5	83.3%	0	0.0%	6	$\chi 2=0.74$ P=0.86 (NS)
	Rs.11,000 to 20,000	2	14.3%	12	85.7%	0	0.0%	14	
	Rs.21,000 to 30,000	0	0.0%	4	100.0%	0	0.0%	4	
	> Rs.30,000	1	16.7%	5	83.3%	0	0.0%	6	

Demographic variables		Post-test CPOT						N	Chi square test
		Mild		Moderate		Severe			
		n	%	n	%	n	%		
Marital status	Married	4	14.8%	23	85.2%	0	0.0%	27	$\chi 2=0.51$ P=0.47 (NS)
	Unmarried	0	0.0%	3	100.0%	0	0.0%	3	
	Separated	0	0.0%	0	0.0%	0	0.0%	0	
	Living alone	0	0.0%	0	0.0%	0	0.0%	0	
Co-Morbidity	Diabetic mellitus	0	0.0%	4	100.0%	0	0.0%	4	$\chi 2=6.53$ P=0.08 (NS)
	Hypertension	2	66.7%	1	33.3%	0	0.0%	3	
	CAD	0	0.0%	0	0.0%	0	0.0%	0	
	DM +HT	0	0.0%	2	100.0%	0	0.0%	2	
	Nil	2	9.5%	19	90.5%	0	0.0%	21	

The above table shows non-association between posttest CPOT score and demographic variables among control group.

CHATER V
DISCUSSION SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

This chapter deals with the discussion of the study with appropriate literature review, statistical analysis and findings of the study based on objectives of the study.

The aim of the study was to evaluate the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation. True experimental pretest post-test control group design was used to assess the effectiveness of music therapy.

Total 60 patients on mechanical ventilation were selected from the TICU & SICU. The samples were selected using simple random sampling method.

Discussion of demographic variables

From the above table, with regard to age 50% (15) of them belongs to 50 years and above and 30% (9) of them were used between 30 – 40 years, in experimental and control group respectively Majority 80% (24) of them were males in both. With regard to education, 36.67% (11) of them were graduates in experimental and 50% (15) in control group. About 40% (12) were private employed in experimental group, whereas in control group this figured more than 57% (17). More than half of them in experimental group were drawing a monthly income of Rs 11,000-20,000, in were as control group this scored about 47% (14). Majority were married in both groups. There was no associated co-morbidity found in experimental group 57% (17) and control group70% (21).

Description of Characteristics of participants:

With regards to the heart rate, in experimental group about 63.33%(19) of them have 61 – 80 beats and in control group 50%(15) of them have 61 – 80 beats. In experimental group with the regards of systolic pressure about 53.33%(16) of them were between 121 – 140 mm/hg. In control group 46.67%(14) of them were between 121 – 140 mm/hg. With the regards of diastolic pressure in experimental group about 70%(21) of them were between 61 – 80 mm/hg. In control group 63.33%(19) of them were between 61 – 80 mm/hg. The distribution shows that the respiration, in experimental group about 46.67%(14) of them have 11 - 20 breaths, 46.67%(14) of them have 21 – 30 breaths. In control group about 56.67%(17) of them have 21 – 30 breaths. With the regards of mode of ventilation in experimental group 43.43%(13) were on CPAP mode and 56.67% (17) were on PCV mode and in control group 56. 67% (17) were on CPAP mode, 43.43%(13) were on PCV mode.

Findings based on objectives

The first objective was to assess the level of pain and physiological parameters among patients on mechanical ventilation.

The mean and SD of pre-test pain level in experimental group as measured by CPOT scores were 6.13 (0.93) and the scores in post-test were, 3.00 (1.20). The pre-test physiological mean and SD scores for heart rate was 2.17 (0.64) with the systolic blood pressure 3.00 (0.69) diastolic 2.17 (0.53) and the respiratory rate was 1.67 (0.71). The post-test mean and SD scores of physiological parameters were

heart rate 2.19 (0.71), systolic blood pressure 2.60 (0.72), diastolic pressure 2.00 (0.45), respiration was 1.53(0.14) and shows efficiency of music therapy on pain and physiological parameters.

Present study was consistent with the study of **Seitzh.et.cl**, 2016 who assessed physiological responses to an early standardized passive exercise protocol to prevent muscle weakness in adults receiving mechanical ventilation and the Behavioural Pain Scale was used to measure patients' comfort along with heart rate, mean blood pressure and oxygen saturation. A quasi-experimental within-subjects repeated measures design was used. Within 72 hours of intubation, 30 patients had 20 minutes of bilateral passive leg movement delivered by continuous-passive-motion machines at a standardized rate and flexion-extension. Repeated measures analysis of variance was used to analyze the effect of the exercise on independent variables. The study concluded that the exercise was well tolerated, with pain relief and improved physiological parameters which enhanced comfort during and after the intervention.

The second objective was to evaluate the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation.

The pretest experimental group CPOT score was 6.13(.93). In control group CPOT score was 6.00 (1.14), there was no significant difference between experiment and control group CPOT score. The above table reveals that in posttest, the experimental CPOT score as 3(1.20). In control group score was 5.43 (.63). The above table reveals that in pretest the experimental group had their mean (SD) heart

rate score as 2.17 (0.64) and systolic blood pressure as 3.00 (0.69) and diastolic blood pressure score was 2.17 (0.53) and respiratory rate score was 1.67 (0.71). In experimental group post-test were heart rate score was 2.19 (0.71) and systolic blood pressure score was 2.60 (0.72), and diastolic blood pressure score was 2.00(0.45) and respiratory score was 1.53 (0.14). Significant difference was found between pretest and posttest systolic blood pressure, diastolic blood pressure and respiratory scores. **there is significant difference between pain and physiological parameters in experiment and control group of CPOT scores proves music therapy effectiveness**

Present study was consistent with the findings of **Ahlers., 2016** who conducted a randomized controlled trial using music therapy on mechanical ventilated patients in order to reduce pain. In 10 months period they admitted 60 patients receiving mechanical ventilation support to intervention (n=30), and control arms (n=30) of a pragmatic parallel group randomized controlled trial. Participants in both arms wore head phones for 90 minutes. Those in the intervention arm heard pleasant natural sound, while those in the control arm heard nothing. Outcome measures reported the self-reported visual analog scale for pain at baseline and 30, 60, 90 minutes into the intervention. The trail arms were similar at baseline. In the intervention arm, pain scores fell and were significantly lower than in the control arm at each time point($P<0.05$). their findings concluded that the administration of pleasant natural sounds via headphones as a simple, safe, non-pharmacologic nursing intervention to reduce the pain for in patients receiving mechanical ventilation support**.**

The third objective was to associate the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic and clinical variables.

In experiment group there was an association found between posttest level of CPOT score and demographic variables among male patients with their income 10,00-20,000. The control group had no association between posttest CPOT score and demographic variables.

The present study findings were contradictory with the study of **Manal, 2014** who analyzed thepain among 301 mechanically ventilated patients in critical care unit using a cross-sectional descriptive design. The pain levels were assessed using behavioral pain scale. Their mean pain levels were 7.1 during nursing interventions and were significantly associated with age group and past history.

SUMMARY

The purpose of the study was to determine the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation. The study was conducted in KMCH Coimbatore.

Objectives of the study were to

a. assess the level of pain and physiological parameters among patients on mechanical ventilation.

b. evaluate the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation.

c. associate the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic and clinical variables.

The following hypotheses were tested

H_1: There was a significant difference between the pre-test and post test level of pain and physiological parameters among participants in music therapy group

H_2: There was a significant difference between post test level of pain and physiological parameters in experimental and control group patients in the music therapy and conventional each group.

H_3: There was a significant association between the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic and clinical variables

The true experimental pretest and posttest control design was adopted for this study. The population of the study was 60 samples (experimental group 30) and (control group 30) who were mechanical ventilated patients. The conceptual framework adopted was Weiden Bach (1954) helping art of clinical nursing theory. The study was conducted for 6 weeks in intensive care unit at KMCH. The samples were selected by non-probability purposive sampling technique. The data was collected on demographic data, critical care pain observation tool and physiological tool for assessing pain and physiological parameters among patients on mechanical ventilation. After conducting pre-test for pain and physiological parameters among

experimental group and control group only experimental group was administered with music therapy intervention and control group had no intervention. The music therapy was administered for 20 minutes; the post test was done 20 minutes after administration of music therapy in experimental group. The conventional group had only routine care and post test was done without music therapy intervention. The descriptive and inferential statistics were done for the statistical analysis. Paired 't' test was used to assess the effectiveness of pain and physiological parameters among music therapy group and conventional group. Independent 't' test was used to compare the pretest and post test values among music therapy group and conventional group. Chi- square was used to find association between the post test CPOT and demographic variables for experimental group. Association between post test CPOT and demographic variables were found for control group.

Major findings of the study

- This study attempted to find out the music therapy on pain and physiological parameters among patients on mechanical ventilation
- The distribution shows that the posttest level of pain in experimental group were 70 %(21) had mild pain and 30 %(9) of them had moderate pain. In control group, 87% (26) of them had moderate pain and 13% (4) of them had severe pain.
- In experimental group, the paired t-test showed significant difference between pre-test CPOT mean score 6.13 with the SD of 0.93 and post-test 3.00 with the SD of 1.20. The mean CPOT scores 3.13 also showed significant differences at $p< 0.001$ level which proves the effectiveness of music therapy.

- The experimental group pre-test had their mean (SD) heart rate score as 2.17 (0.64) and systolic blood pressure as 3.00 (0.69) and diastolic blood pressure score was 2.17 (0.53) and respiratory rate score was 1.67 (0.71). In control group the heart rate score was 2.19 (0.71) and systolic blood pressure score was 2.60 (0.72), and diastolic blood pressure score was 2.00(0.45) and respiratory score was 1.53 (0.14). Significant difference was found between pre-test and post-test systolic blood pressure, diastolic blood pressure and respiratory scores except heart rate score
- The above table reveals that in pre-test the experimental group CPOT score was 6.13(.93). In control group CPOT score was 6.00 (1.14), there was no significant difference between experiment and control group CPOT score. The above table reveals that in post-test, the experimental CPOT score as 3(1.20). In control group score was 5.43 (.63). The significant difference between experiment and control group of CPOT scores proved music therapy effectiveness.

The distribution showed the association between post-test level of CPOT score and demographic variables among experiment group. There was strong association between CPOT scores with demographic variable male patient and whose' income ranged between 10, 000-20,000 rupees per month. The association between post-test CPOT score and demographic variables among control group were not significantly associated which was confirmed using chi square test.

CONCLUSION

The statistical evidence proved that the music therapy had reduced the level of pain and physiological parameters among patients on mechanical ventilation when compared with the control group. Hence the researcher concluded that the music therapy was effective.

Nursing Implication

The Study findings have implications for various areas of nursing practice, nursing education, nursing administration and nursing research.

Implications in Nursing Practice

The above study has following implications on nursing practice

- Music therapy can be introduced as a clinical routine in critical care.
- Music therapy can be an integral part of the routine care to reduce the pain

Implications in Nursing Education:

The above study has following implications on nursing education

- The nurse educator must be able to correlate the pain which is determined to the health status of an individual.
- The nurse educator must create awareness on various divisional therapies such as music for reducing the pain of the individual.

Implications in Nursing Research

The above study has following implications on nursing research

- Nursing research on music therapy will be a valuable reference material for further research.
- Quality study can be undertaken to assess the self-report of the participants.

Recommendations

The investigator recommended the following studies to strengthen the nursing care

- The study can be replicated on larger sample.
- This study can be conducted on other areas like medical wards.
- This study can be conducted by using different research design like qualitative study.

ABSTRACT

The study entitled “A study to assess the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation at KMCH, Coimbatore. **Objective:** The aim of the study was to assess the level of pain and physiological parameters among patients on mechanical ventilation and evaluate the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation and associate the level of pain and physiological parameters among patients on mechanical ventilation with their selected demographic variables. **Design:** True experimental pre-test and post-test control group design was used. **Setting:** Truma intensive care unit and surgical intensive care unit of Kovai Medical Center and Hospital, Coimbatore. **Sample size:** Totally 60 samples (30 samples experimental group) and (30 samples control group**). Conceptual framework:** Modified Weiden Bach (1954) Helping art of clinical nursing theory was used. **Data collection procedure:** The data collected were demographic variables, CPOT scale and physiological parameters on mechanical ventilation among music therapy group and control group. **Intervention:** Music therapy described the pre-recorded validated music (violin) which was played using head phone, for about 20 minutes. **Results:** The subject who received the intervention had reduced pain and physiological parameters among patients on mechanical ventilation. **Conclusion:** The study results supported music therapy as one of the non pharmacological intervention and it helped to reduce pain and physiological parameters among patients on mechanical ventilation.

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APPENDIX-A

DEMOGRAPHIC VARIABLES OF PATIENTS MECHANICAL VENTILATION

SAMPLE NUMBER _____

DEMOGRAPHIC DATA

1. AGE :

   A) 20-30 years

   B) 31-40 years

   C) 41-50 years

   D) above 50 years

2. SEX :

   A) Male

   B) Female

3. EDUCATION

   A) Primary

   B) Secondary

   C) Graduated

   D) Illiterate

4. OCCUPATION

   A) Private

   B) Government

   C) Self employee

   D) Un employee

5. INCOME

A) <10,000

B) 11,000 to 20,000

C) 21,000 to 30,000

D) Above 31,000

E) Nill

6. MARRIAGE STATUS

A) Married

B) Unmarried

C) Separated

D) Living alone

7. CO- MORBIDITY

A) Diabetic mellitus

B) Hypertension

C) Coronary artery diseases

D) Diabetic mellitus and hypertension

E) Nill

Indicator	Description	Score
Facial Expressions	0 = Relaxed: neutral facial expression 1 = Tense: Frowning, brow-lowering, orbit tightening, &/or levator contraction 2 = Grimace: All of facial criteria a bove plus eyelids tightly closed	
Body Movements	0 = Absence of movements: (does not necessarily mean no pain) 1 = Protection/guard, withdraws: Slow, cautious movements, rubs pain site 2 = Restlessness/thrashing: Pulls tube, attempt to sit, climb out of bed, thrash, strikes out	
Muscle Tension Evaluate w/ passive flexion /extension of arms	0 = Relaxed: No resistance to passive arm movement 1 = Tense, rigid: Resists to passive arm movement 2 = Very tense, rigid: Strong resistance to passive movement	
Ventilation compliance -or- Vocalization (if extubated)	**Ventilated Patient or Extubated, "vocal" Patient** 0 = Tolerating ventilator, no alarms 0 = Quiet/normal tone 1 = Intermittent alarms, stop spontaneously, coughing 1 = Sigh, moaning 2 = Fight ventilator/asynchrony, frequent alarms 2 = Crying out, sobbing	
Pain with Movement Evidence of pain (e.g. above behavior or individualized response) while providing usual care (e.g. turning).	0 = No sign of pain while providing care 1 = Resists movement / guards against certain movements 2 = Pain behaviors (e.g. grimace, withdraws, vocalization, sudden HR or BP spike) with movement associated with routine care or provided treatments	
	TOTAL:	

PHYSIOLOGICAL VARIBLES

1. Heart rate

A) 41-60 b/m

B) 61-80 b/m

C) 81-100 b/m

D) >101 b/m

2. Blood Pressure

Systolic Pressure

A) 81-100 mm\hg

B) 101-120 mm\hg

C) 121-140 mm\hg

D) >141

Diastolic Pressure

A) 41- 60 mm\hg

B) 61- 80 mm\hg

C) 81-100 mm\hg

D) 101- 120 mm\hg

3. Respiration

A) 11-20 breaths

B) 21-30 breaths

C) >31breaths

LIST OF EXPERTS

1. **Prof. Dr. S.MADHAVI, M.Sc. (N), Ph.D.,**
   Principal,
   KMCH College of Nursing,
   Coimbatore-641014.

2. **Dr. N. SELVARAJAN., M.D(ANAESTHESIA)., FICM.,**
   Head of the Department.
   Department of Anaesthesia and critical care medicine,
   Kovai Medical Center and Hospital,
   Coimbatore-14.

3. **Prof.DR.P.VIJI, M.Sc(N), Ph.D.,**
   Department of Medical Surgical Nursing ,
   KMCH College of Nursing,
   Coimbatore-641014.

4. **Prof. Dr. K.BALASUBRAMANIAN, M.Sc(N), Ph.D.,**
   Department of Medical Surgical Nursing,
   KMCH College of Nursing,
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5. **Prof.DR.P.AKILA, M.Sc. (N), Ph.D.,**
   Department of Medical Surgical Nursing,
   KMCH College of Nursing,
   Coimbatore-641014.

6. **Prof.P.KUZHANTHAIVEL,M.Sc (N).,**
   Department of Medical Surgical Nursing,
   KMCH College of Nursing,
   Coimbatore-641014.

KMCH COLLEGE OF NURSING

(Approved by the Government of Tamil Nadu & The Tamil Nadu Nurses & Midwives Council, Chennai.
Recognized by the Indian Nursing Council, New Delhi and Affiliated to the Tamil Nadu Dr. M.G.R. Medical University, Chennai)
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Prof. DR. S. Madhavi, M.Sc(N)., Ph.D., **08-03-2018**
Principal

Ref No. KMCT/6227/03/18

To
Dr. N. Selvarajan M.D(Anaesthesia)., FICM.,
HOD- Department of Anaestnesia & Critical Care Medicine
Kovai Medical Center and Hospital
Coimbatore -14

Dear Sir

Greetings to you from KMCH College of Nursing

I Submit that one of Our M.Sc(N) II year student by name Mr. Gopalakrishnan. M Specializing in Medical Surgical Nursing in our College desires to conduct a Study titled **" A Study to Assess the effectiveness of Music Therapy on pain and physiological parameters among patients on Mechanical Ventilation at Kovai Medical Center and Hospital, Coimbatore."** as a part of his M.Sc(N) Curriculum.

As he is in need of Medical Expert to complete the study, I request you to guide the student.

Thanking you.

Yours Truly,

Principal

The Principal
K.M.C.H. College of Nursing
P.B. No. : 3209, Avanashi Road,
Coimbatore - 641 014.

7/8/18

Dr.N.Selvarajan, MD (Anaes - AIIMS), FICCM,
Head - Department of Critical Care Medicine
TN.Reg.No : 30418
Kovai Medical Center & Hospital Ltd
99, Avanashi Road, Coimbatore - 641 014

KMCH ETHICS COMMITTEE
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EC Reg. No : ECR / 112 / Inst / TN / 2013

Ref: EC/AP/611/04/2018
23.04.2018

APPROVED

To

Dr. P. Viji, M.Sc. (N), Ph.D,
Professor – Department of Medical Surgical Nursing,
KMCH College of Nursing,
Coimbatore – 641 014.

Dear Dr. P. Viji,

The proposal entitled **"A study to assess the effectiveness of music therapy on pain and physiological parameters among patients on mechanical ventilation at KMCH, Coimbatore"**, submitted by **Mr. M. Gopalakrishnan,** under your supervision was reviewed by the Ethics Committee in its meeting held on **21.04.2018** and grants ethical clearance for the study .

Regards,
Yours Sincerely,

06/8/18

Dr.M.S. Thamizharasi,
Chairperson,
KMCH Ethics Committee.

Dr. M.S.Thamizharasi
M.D.,D.G.O.,PG Dip (Psych)
Chairperson
Ethics Committee
Kovai Medical Center and Hospital
Coimbatore - 641 014

Copy to Clinical Guide:

Dr. N. Selvarajan, MD (Anaes), FICM,
Head of the Department – Anaesthesiology,
Crtical Care Medicine, Kovai Medical Center and Hospital,
Coimbatore – 641 014

ETHICS COMMITTEE

KMCH ETHICS COMMITTEE
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EC Reg. No : ECR / 112 / Inst / TN / 2013

KMCH ETHICS COMMITTEE MEMBERS LIST

S. No	Member Name	Designation	Representation	Designation To The Institution	Gender
1.	Dr.M.S. Thamizharasi	Retired Senior Civil Surgeon, Tamil Nadu Govt service	Chairperson	None	F
2	Dr. Devdas Madhavan	Consultant Urologist	Member Secretary	Consultant Urologist	M
3	Dr. V.Rajamani	Consultant Rheumatologist & Physician	Clinician	Consultant Rheumatologist & Physician	M
4	Dr.K. Senthilkumar	MD-Pharmacology Pharmacologist	Basic Medical Scientist	None	M
5	Dr.N. Selvarajan	Consultant Anaesthesiologist	Clinician	Consultant Anaesthesiologist	M
6	Dr. Sangita S.Mehta	Consultant Pathologist	Clinician	Consultant Pathologist	F
7	Dr. S.Madhavi	Principal	Member	Principal, KMCH college of Nursing	F
8	Dr. K.S.G.Arul Kumaran	Professor	Basic Medical Scientist	Professor, KMCH college of Pharmacy	M
9	Dr.K.S. Selvanayaki	Tamil Nadu Institute of Urban Studies (State).	Social Scientist	None	F
10	Mr. C.Tamil Selvan	VP-Materials	Convener	VP-Materials	M
11	Mr. T.C.Dinamani	Legal Advisor	Legal Expert	None	M
12	Mr.R.Krishnamoorthy	Priest	Theologist	Priest	M
13	Mr.K. Beno Micheal	Self-Employee	Lay person	Self-Employee	M

06/8/18

Dr.M.S. Thamizharasi
Chairperson
KMCH Ethics Committee

Dr. M.S.Thamizharasi
M.D.,D.G.O.,PG Dip (Psych)
Chairperson
Ethics Committee
Kovai Medical Center and Hospital
Coimbatore - 641 014

ETHICS COMMITTEE

CERTIFICATE OF CONTENT VALIDITY

This is to certify that I have perused that Research proposal submitted by Reg No : 301610453 entitled as **"A study to assess the Effectiveness of Music therapy on Pain and Physiological Parameters among patients on Mechanical ventilation at KMCH, Coimbatore"**

I found that Methodology of the content and tool are appropriate.

Date: 26/4/18

Signature & seal

Department of Critical Care Medi...
Kovai Medical Center and Hospit...
Avanashi Road, Coimbatore - 641 ...
Ph : 0422 - 4323200

CERTIFICATE OF CONTENT VALIDITY

This is to certify that I have perused that Research proposal submitted by Reg No : 301610453 entitled as **"A study to assess the Effectiveness of Music therapy on Pain and Physiological Parameters among patients on Mechanical ventilation at KMCH, Coimbatore"**

I found that Methodology of the content and tool are appropriate.

Date: 27/4/18

Signature & seal

CERTIFICATE OF CONTENT VALIDITY

This is to certify that I have perused that Research proposal submitted by Reg No : 301610453 entitled as **"A study to assess the Effectiveness of Music therapy on Pain and Physiological Parameters among patients on Mechanical ventilation at KMCH, Coimbatore"**

I found that Methodology of the content and tool are appropriate.

Date: 30/4/18

Signature & seal